Summary of the
NELAC Policy and Program Structure Committee Teleconference
September 25, 1996

The Policy and Program Structure Committee of the National Environmental Laboratory Accreditation Conference (NELAC) convened by teleconference on September 25, 1996, at 1 pm. The committee meeting was led by its chair, Dr. Kenneth Jackson of the New York State Department of Health. The purpose of this meeting was to continue discussing revisions proposed for Sections 1.8 and 1.9 of Chapter 1 of the standards. A list of action items is provided in Attachment A. A list of participants is given in Attachment B. A copy of wording proposed by Ms. Marlene Moore of Advanced Systems, as indicated in the action list from the previous teleconference, is given in Attachment C. A copy of Sections 1.8 and 1.9, revised to include the previously agreed upon changes, is given in Attachment D.

1. MISCELLANEOUS ITEMS

Dr. Jackson welcomed Mr. Robert Luna of as a new member of this committee. He noted that the revised sections, faxed September 24, 1996, contain the changes made by this committee in its previous conference call; this includes changes to Figure 1-3.

2. SECTION 1.9.1 Overview

The proposed rewording of the second paragraph of Attachment D, as suggested by Attachment C, was discussed and accepted. It was suggested that material following the asterisk be changed to read:

> In some RCRA and other EPA programs the regulations mandate the method to be followed for reporting data. For some waste testing the RCRA SW-846 methods are to be considered guidance. In the example above, an accredited laboratory is required to conform with the NELAC chapter 5, Appendix D.1 and method specific criteria. The laboratory must be familiar with the RCRA requirements and, if the test method is mandated, the specific regulatory RCRA program criteria must be followed.

The last paragraph of this section was discussed. The committee reiterated that the intention of supplemental accreditation should be of limited scope, and added a final phrase to the last sentence so that it now reads "Any supplemental requirements essential to meet the specific needs of an accrediting authority would be added at the method-specific or analyte level *and must be approved by NELAC*."

3. SECTION 1.9.2 General Laboratory Requirements

It was recommended that the wording of this section not refer to other laws, particularly in terms of possible enforcement of those laws. Following discussion, it was agreed to delete the sentence:

> "General requirements shall include Health and Safety, and Waste Management Programs. Applicant laboratories shall be required to be in compliance with all applicable

federal, state, and local rules and regulations covering environmental and occupational health and safety."

Additional wording changes to this paragraph are given in *italics*:

"Responsibility for the evaluation of compliance with these *and other* rules and regulations shall remain with the appropriate regulatory body. *Accreditation* under NELAC *should* not be considered to be a judgement that the laboratory is in compliance with any other environmental control or occupational health statute or regulation, either Federal or State."

The last paragraph was altered, with changes given in *italics*, to read:

"The following requirements are presented *as an overview of the laboratory requirements* and reference is given to the relevant sections of Chapter 5 (Quality Systems), where full details may be found."

Section 1.9.2.3 Personnel
It was agreed that this section should be altered to refer to the corresponding section in Chapter 5, "Quality Systems."

Sections 1.9.2.4 - 1.9.2.7, 1.9.2.9, and 1.9.2.10
These sections were accepted without change.

Section 1.9.2.8 Test Methods
This section was changed to read: "The laboratory shall document, *in SOPs*, instructions on the use and operation of all relevant equipment, on the handling and preparation of samples for calibration and *performance of* testing."

Section 1.9.2.11 Sub-contracting of calibration or testing
This section was changed to read "*When a laboratory seeks to subcontract work pursuant to EPA measurement program, it may do so* only to another laboratory that is also appropriately accredited by a NELAC accrediting authority. Subcontractors must be clearly identified *in the test report* and documentation describing the *accreditation* status ..."

Section 1.9.2.12 Outside support services and supplies
This section was changed to read: "The laboratory shall use only those outside support services and supplies that are of adequate quality *to sustain confidence in a laboratory's tests.*

Section 1.9.2.13 Complaints
Mr. Jerry Parr indicated that he would like the opportunity to obtain a legal review of this section prior to the next conference call.

NEXT TELECONFERENCE

The next scheduled teleconference of this committee is Wednesday, October 9, at 1 pm Eastern Time to continue discussion of Section 1.9.2. Additional teleconferences are scheduled for October 30 and November 13; all are planned to begin at 1pm.

Attachment-A

ACTION ITEMS
Policy and Program Structure Committee Teleconference
September 25, 1996

Action	Date Completed
Mr. Jerry Parr will obtain legal review of Section 1.9.2.13 for discussion at the October 9 teleconference.	

Attachment B

LIST OF PARTICIPANTS
Policy and Program Structure Committee Teleconference
September 25, 1996

Name	Affiliation	Telephones
Pauline Bouchard	MN Department of Health	T: 612/623-5331 F: 612/623-5514
Henry Bradford	LA Dept of Health and Hospitals	T: 504/568-2545 F: 504/568-5393
Ted Coopwood, NELAC Executive Secretary	USEPA, NELAP	T: 202/233-9358 F: 202/233-9651
Marcia Davies	US Army, Corps of Engineers	T: 402/697-2555 F: 402/697-2595
Ken Jackson, Chair	NY State Department of Health	T: 518/485-5570 F: 518/485-5568
Robert Luna	City of Longmont, CO	T: 303/651-8666 F: 303/682-9543
Tom McAninch	Eastman Chemical Co.	T: 903/237-5473 F: 903/2376395
Marlene Moore	Advanced Systems, Inc.	T: 302/834-9796 F: 302/995-1086
Jerry Parr	Quanterra Environmental Services	T: 303/421-6611 F: 303/567-9136
Pat Royal	Springborn Laboratories, Inc.	T: 508/295-2550 F: 508/295-8107
Gene Tatsch, Support Contractor	Research Triangle Institute	T: 919/541-6930 F: 919/541-7386

Page 3 - 1.9.1 second paragraph - proposed revised wording.

Under the tiered approach, a laboratory must meet the basic requirements and those additional specific tiers of requirements that are linked to the basic requirements for a particular test or activity. For example, a laboratory seeking accreditation in hazardous waste organic testing under the auspices of RCRA must meet all the requirements listed in general laboratory (NELAC Chapter 5), chemistry (NELAC Appendix D.1), RCRA regulations (40CFR261), and the method (s) used (SW-846 5030/8240). *In some cases RCRA and other EPA programs, the regulations mandate the method to be followed for reporting data. For some waste testing the RCRA program suggests the methods to be followed. In the example, an accredited laboratory is required to perform the NELAC chapter 5, Appendix D.1 and method specific criteria. The laboratory must be familiar with the RCRA requirements and if testing is known to be performed for specific regulatory reporting any additional RCRA program specific criteria must be followed.

*We may want to end the example here.

Sections 1.8 and 1.9 (originally 1.5 and 1.6)
K. W. Jackson, September 23, 1996

1.8 SCOPE OF NELAC

The scope of NELAC shall encompass the necessary scientific testing to serve the needs of the States, United States Environmental Protection Agency (USEPA), and other Federal agencies involved in the generation and use of environmental data, where such generation or use is mandated by statutes and pursuant regulations. A laboratory is encouraged to use the NELAC standards for all other tests.

Applicable Federal statutes include the Clean Air Act (CAA); the Comprehensive Environmental Response Compensation and Liability Act (CERCLA); the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA); the Federal Water Pollution Control Act (Clean Water Act; CWA); the Resource Conservation and Recovery Act (RCRA); the Safe Drinking Water Act (SDWA); and the Toxic Substances Control Act (TSCA). The standards shall also include provisions to permit special requirements or fields of testing promulgated by any of the accrediting authorities.

The standards shall not be implemented or administered in a way which limits the ability of local, state or federal agencies to investigate and prosecute enforcement cases. Specifically, when engaged in the collection and analysis of forensic evidence to support litigation, those agencies may use any procedure that is appropriate given the nature of the investigation, subject only to the bounds of sound scientific practice. The standards shall not apply to governmental laboratories engaged solely in the analysis of forensic evidence.

1.9 ORGANIZATION OF THE ACCREDITATION REQUIREMENTS

1.9.1 Overview

The accreditation requirements shall be based on fields of testing, using the tiered approach shown in Figure 1-3. Accreditation will be granted for the use of specified approved methods, and on an individual analyte basis; e.g., a laboratory determining lead by both inductively-coupled plasma mass spectrometry (USEPA method 200.8) and graphite furnace atomic absorption spectrometry (USEPA method 200.9) would require accreditation for lead by method 200.8 and lead by method 200.9. Loss of accreditation for an analyte would not automatically result in loss of all other analytes accredited under the methods, provided the laboratory remained proficient in the determination of the other analytes.

Under the tiered approach, a laboratory must meet the basic requirements, and those additional specific tiers of requirements that are linked to the basic requirements for a particular test or activity; e.g., a laboratory seeking accreditation in hazardous waste organic testing under the auspices of RCRA must meet all the requirements listed in general laboratory, chemistry, RCRA, and the method(s) used. In most cases, USEPA program-specific requirements will be limited to the use of the mandated or permit-specified method; e.g., *[Marlene will provide an example?]*

The field of testing structure provides flexibility by allowing for the incorporation of new methods or new instrumentation without the applicants repeatedly demonstrating the basic requirements. This scheme eliminates redundancy, and structures appropriate and specific accreditation requirements to meet the needs of environmental laws and regulations. Regulators are thus provided with environmental sample testing results generated by laboratories according to specified or demonstrably equivalent methods and quality assurance protocols. Additionally, the adoption of method-specific, analyte and supplemental classifications allows for the design of accreditation to suit needs of individual laboratories and accrediting authorities. This flexibility shall promote reciprocity among all the participating accrediting authorities. The field of testing approach proposed shall also allow for the future incorporation of performance based methods (PBM) by substituting an approved PBM for the specified analytical methods.

In addition, a category of supplemental accreditation is designated for additional methods or analytes required by an accrediting authority. Supplemental accreditation shall be reserved for methods or analytes that are not required under any of the federal programs that are part of NELAC, and it shall not be used to modify any NELAC standards for analytes or methods. Any supplemental requirements essential to meet the specific needs of an accrediting authority would be added at the method-specific or analyte level.

1.9.2 General Laboratory Requirements

The general requirements are applicable to all laboratory applicants regardless of their size, volume of business, or field of testing. The organizational structure, or procedures used by applicant laboratory organizations to meet these general requirements may differ as a function of size or scope of testing of an organization. The general requirements shall include all the elements outlined in General Requirements for the Competence of Calibration and Testing Laboratories, ISO/IEC Guide 25: 1990 (E). General requirements shall include health and Safety, and Waster management Programs. Applicant laboratories shall be

required to be in compliance with all applicable federal, state, and local rules and regulations covering environmental and occupational health and safety. Responsibility for the evaluation of compliance with these rules and regulations shall remain with the appropriate regulatory body. Certification under NELAC cannot be considered to be a judgment that the laboratory is in compliance with any other environmental control or occupational health statute or regulation, either Federal or State.

1.9.2.1 Organization and Management

The laboratory shall be legally identifiable, and shall have managerial staff with the authority and resources needed to discharge their duties. This includes technical management with overall responsibility for the technical operations, and quality management with responsibility for the quality system and its implementation.

1.9.2.2 Quality System, Audit and Review

The laboratory shall establish and maintain a quality system appropriate to the type, range, and volume of calibration and testing activities it undertakes. The quality manual, and related quality documentation, shall state the laboratory's policies and operational procedures. The laboratory shall arrange for audits of its activities at appropriate intervals to verify that is operations continue to comply with the requirements of the quality system.

1.9.2.3 Personnel

The laboratory shall have sufficient personnel having the necessary education, training, technical knowledge and experience for their assigned functions.

1.9.2.4 Accommodation and Environment

Laboratory facilities shall have suitable space, energy sources, lighting, heating and ventilation for proper performance of tests.

1.9.2.5 Equipment and Reference Materials

The laboratory shall be furnished with all items of equipment (including reference materials) required for the correct performance of tests for which accreditation is sought.

1.9.2.6 Measurement Traceability and Calibration

All measuring and testing equipment having an effect on the accuracy or validity of tests shall be calibrated and/or verified before being put into service. A system for calibration and/or verification must be documented. Standards used for calibration must be traceable to national standards of measurement where available.

1.9.2.7 Documentation and Labeling of Standards and Reagents

The laboratory shall retain records of the origin, purity, and traceability of all standards (including balance weights and thermometers) and reagents. These records shall include the date of receipt, storage conditions, and, if applicable, the date of opening and an expiration date.

1.9.2.8 Calibration and Test Methods

The laboratory shall document instructions on the use and operation of all relevant equipment, on the handling and preparation of samples, and for calibration and/or testing.

1.9.2.9 Records

The laboratory shall maintain a record system to suit its particular circumstances and comply with any applicable regulations. This shall include a means of sample tracking, a sample acceptance policy, sample receipt protocol, storage conditions, and calibration and test results.

1.9.2.10 Reports

All test results shall be reported in accordance with any instructions in the test methods, and shall include all the information necessary for the interpretation of the test results and all information required by the method used.

1.9.2.11 Sub-Contracting of Calibration or Testing

The accredited laboratory shall sub-contract work only to another laboratory that is also appropriately accredited by a NELAC accrediting authority. Subcontractors must be clearly identified and documentation describing the certification status of the subcontractor shall be available for inspection in the

contracting laboratory's records.

1.9.2.12 Outside Support Services and Supplies

The laboratory shall use only those outside support services and supplies that are of adequate quality.

1.9.2.13 Complaints

The laboratory shall have documented policy and procedures for the resolution of complaints received from clients or other parties about the laboratory's activities, with records maintained of all complaints and of the actions taken by the laboratory. Where a complaint, or any other circumstance, has raised doubt concerning the procedures, or other requirements or otherwise concerning the quality of the organization's calibrations or tests, the laboratory shall be promptly audited in accordance with pre-established internal procedures. Where a laboratory, or any individual associated with the laboratory, is the subject of a charge of data fraud, or falsification of data, the laboratory management shall immediately notify the primary accrediting authority and request a complete investigation. This investigation by the accrediting authority shall be in addition to any internal investigation initiated by the management of the laboratory.

1.9.3 General Field Testing Requirements

(To be developed)

1.9.4 Chemistry Requirements

1.9.4.1 Positive and Negative Controls

The laboratory shall perform method blanks and matrix spikes, shall analyze quality control check samples, and, where appropriate, shall add surrogate compounds to samples, standards and blanks.

1.9.4.2 Analytical Performance Characteristics

For all methods, demonstration of analytical capability shall be performed initially and whenever a significant change occurs, such as new analyst, instrument or technique. Appropriate calibration protocols shall be followed. Satisfactory on-going precision and accuracy shall be assured through the analysis of

duplicates and proficiency test samples respectively. Method detection limits shall be determined. The selectivity of chromatographic methods shall be established.

1.9.4.3 Test Conditions

All test instruments shall operate consistently within the specifications of the test methods. Glassware, reagents, and diluent water shall meet the purity requirements of the test methods.

1.9.5 Whole Effluent Toxicity Requirements

1.9.5.1 Positive and Negative Controls

The laboratory shall demonstrate its ability to obtain consistent results through the use of reference toxicants. Negative controls shall be those specified by the methods.

1.9.5.2 Analytical Performance Characteristics

Precision shall be determined on an on-going basis through the use of reference toxicant tests and related control charts. Test sensitivity shall be established as the minimum significant difference between the control and test concentration.

1.9.5.3 Test Conditions

All test instruments shall operate consistently within the specifications of the test methods. Glassware, reagents, and water used for culturing and testing and as a diluent shall meet the purity requirements of the test methods. Test organisms shall be positively identified to species on an annual basis. Culturing and testing of organisms shall be separated to avoid cross-contamination. Cultures and test organisms shall be maintained as specified in the methods. Food used for culturing and testing shall be analyzed for toxic organics and metals. The quantity and type of food given to test organisms shall be consistent with the specifications of the methods. Light intensity, dissolved oxygen, and pH shall be measured at specified time intervals. Maximum permitted sample holding times and temperatures shall not be exceeded.

1.9.6 Microbiology Requirements

1.9.6.1. Positive and Negative Controls

The laboratory shall prepare and analyze blanks and uninoculated controls as specified by the method. Additionally, for each item of equipment used in preparing samples for incubation, there shall be at least one control at the beginning, end, and after each tenth sample. At least one pure culture of a known positive reaction shall be included monthly.

1.9.6.2 Analytical Performance Characteristics

The laboratory shall, through method validation, establish appropriate performance characteristics for each method used. Satisfactory on-going precision and accuracy shall be assured through the analysis of duplicates and proficiency test samples respectively. Reference cultures shall be used to demonstrate traceability and selectivity.

1.9.6.3 Test Conditions

The laboratory environment shall be sufficiently contamination free, and constant and consistent test conditions shall be assured through the use of an appropriate environmental contamination monitoring program. All test instruments shall operate consistently within the specifications of the test methods. Temperature measurement devices shall be calibrated to national or international standards for temperature, and the stability and uniformity of temperature shall be assured. Autoclaves shall be monitored to perform adequately. All growth and recovery media shall be checked to assure that target organisms respond in an acceptable and predictable manner. The laboratory shall ensure that the quality of reagents and media used is appropriate for the test concerned.

1.9.7 Radioanalysis

(To be developed)

1.9.8 Federal Program and Method Requirements

All additional requirements specified in the methods shall be met.

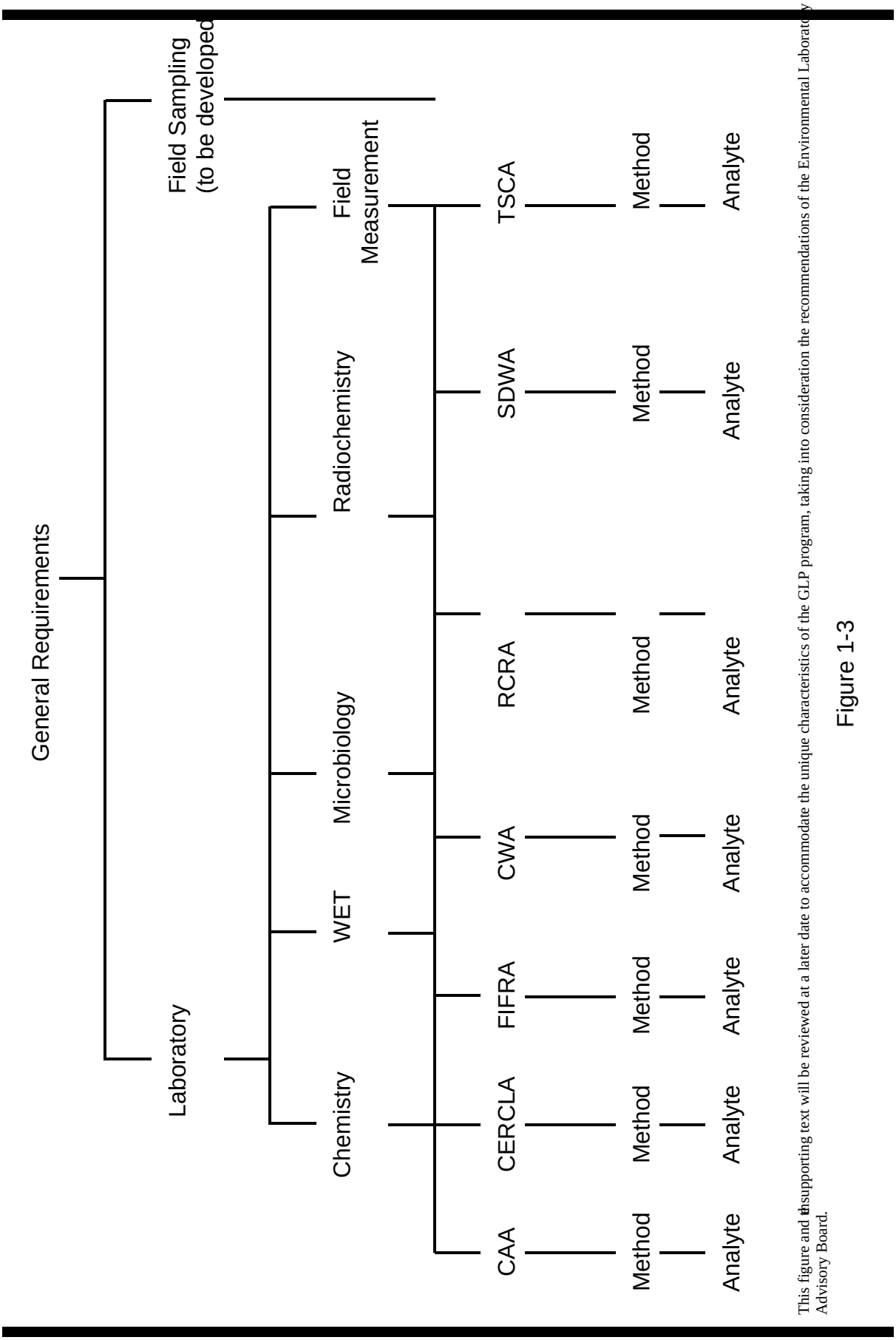

Figure 1-3

This figure and the supporting text will be reviewed at a later date to accommodate the unique characteristics of the GLP program, taking into consideration the recommendations of the Environmental Laboratory Advisory Board.

Attachment D